



Linking People to Knowledge!™

# Global Compliance News

JUNE 2006

VOLUME 3, NUMBER 5

## International Standards

### New Releases:

#### [IEC 60083:](#)

Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC

#### [IEC 60297-3-104:](#)

Mechanical structures for electronic equipment – Dimensions of mechanical structures of the 482,6 mm (19 in) series – Part 3-104: Connector dependent interface dimensions of subracks and plug-in units

#### [IEC 60335-1:](#)

Household and similar electrical appliances – Safety – Part 1: General requirements

#### [IEC 60706-3:](#)

Maintainability of equipment – Part 3: Verification and collection, analysis and presentation of data

#### [IEC 60745-1:](#)

Hand-held motor-operated electric tools – Safety – Part 1: General requirements

#### [IEC 61076-1:](#)

Connectors for electronic equipment – Product requirements – Part 1: Generic specification

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SIMCOM International was the first Company in North America to be awarded the coveted Consultative Agent Status for China's Compulsory Product Certification System by China's Certification and Accreditation Administration.

IEC 61082-1:  
Preparation of documents used in electrotechnology – Part 1: Rules

IEC 62304:  
Medical device software – Software life cycle processes

IEC 62391-1:  
Fixed electric double-layer capacitors for use in electronic equipment – Part 1: General specification

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## **Hot Topics in July's Issue**

### **Overview of Product Regulatory Compliance in the US**

The US has the largest and most technologically powerful economy in the world, with a per capita GDP of \$42,000. In this market-oriented economy, private individuals and business firms make most of the decisions, and the federal and state governments buy needed goods and services predominantly in the private marketplace.

The US economy is integrated and largely self-contained, with every major industry represented. US manufacturers often source components overseas. The USA presents opportunities for foreign companies in all sectors.

The Article in the next issue of Global Compliance news will discuss Product Regulatory Compliance in the USA.

### **What is all the excitement about Nanotechnology?**

First – what is nanometer?

A nanometer is one millionth of a millimeter. The attraction of the technology is that new materials and processes, with functions and properties that cannot be achieved otherwise, can in principle be made through the accurate control at this atomic and molecular level.

#### **What is happening now?**

Globally, more than 180 applications are in different development stages and a few have been commercialized. The nanofood market is expected to exceed \$ 7 billion in the current year. Presently, more than 200 companies around the world are active in research and development. The United States is the leader followed by Japan and China. By 2010 it is expected that Asia with more than 50% of the world population will be the biggest market for Nanofood, led by China.

Next month, Global Compliance News will explore this market including potential its potential compliance issues.

### **Machinery Directive Update**

In the July newsletter, SIMCOM will cover the Machinery Directive Update. On September 17, 2004 the Council of the EU published a Document 12509/04 titled the "Proposal for a Directive of the European Parliament and of the Council on Machinery and amending Directive 95/16/EC (Text with EEA relevance)". This Document is still in the proposal stage, but since the changes will most likely be approved as written, it is important to learn about them at this time. The Article will concentrate on the changes and the implications thereof for the manufacturers and the Notified Bodies.

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## ***The Benefits of Early Implementation of Regulatory Compliance Tasks... Or – How to lower product compliance expense!***

With ever-increasing demand from sales and marketing managers, the challenge of target-market regulatory compliance is daunting. Yet, if design engineers employ regulatory compliance best practices at the inception of product development; numerous benefits will inure to downstream task groups. If standardized design processes are blended into defined plans for indigenous requirements; re-usable benefits will lower overall product compliance expense.

We will examine a vital element of the regulatory compliance process - choosing, interacting and preparing for tasks to be performed by independent test laboratories.

Choosing the right test and certification provider is akin to choosing a “partner”. The word ‘partner’ may sound strange to readers; as many regulatory compliance professionals think of test and certification tasks as mere burdens in the overall compliance scheme. Common misconceptions that increase regulatory compliance expense include:

- ✓ Conformity assessment is quality engineering function that is a last step before product goes into production.
- ✓ Products must be designed to performance specifications whereas testing and certification is merely a cost to the company, without input from the design team.
- ✓ No matter how dissatisfied the company may be with their test and certification provider – the company does not have alternatives.
- ✓ The company has to certify the product for every country where it is to be sold.

Right? -----**Wrong!**

Manufacturers will eliminate thousands of dollars in unnecessary compliance expense and hundreds of man-hours if basic regulatory compliance processes are begun prior to the design or conception phase of a new product.

### **Planning and Assessment Phase:**

The following planning and assessment tasks should be completed prior to the start of any new product design:

- ✓ What are the Regulatory Requirements for each country where the product will be sold?
- ✓ Do the target countries have harmonized regulatory schemes with other countries on the target marketing list such as: Mutual recognition between countries such as within the EU or international recognition schemes such as: The CB Scheme?
- ✓ What standards must be purchased and studied? Are there any compliance requirements in the countries of interest that have long-lead times such as: Telephony permits, Pressure Vessels, etc.?
- ✓ Does the company have the most recent version of any required standard?
- ✓ Have other “older” products been certified to similar schemes?
- ✓ Is there one test and certification organization that offers services in all or, a majority of the target countries? Is the test lab accredited in all disciplines mandated by the target country for your specific product?

### **Design Phase Best Practices:**

During the design phase the design engineer should be armed with all compliance requisites to be applied in combination with the functional specifications. At this time, it is best to evaluate and choose the test and certification provider. With active support from the test and certification provider; design engineers will have support from the entity that passes final judgment on the product’s compliance success; therefore, it is similar to having pre-test conferences with the professor. Questions that arise during design scenarios may be posed to the test lab for supportive solutions in advance of costly testing sessions. We recommend that a



“Preliminary Design Review” be completed by the test lab. Although the review may cause pre-testing expenses; it will certainly be less than being forced into design changes during the test phase. Essentially, one should seek identification of all design-element flaws in advance of actual product testing.

### **Advance Coordination with Key Component Suppliers:**

It is crucial that the OEM identify all critical component suppliers in advance of full-fledged testing with assurance from the supplier that their components will not cause the product to fall-out of compliance during final testing. Alternative critical component suppliers should be brought into the planning phase as well; providing additional security for the OEM. Free substitution of critical components will provide enormous advantages for the purchasing or sourcing team prior to actual production phases.

### **Prototypes:**

It is best to submit a prototype to the test lab early in the design phase and certainly prior to final testing of production product for pre-test evaluation related to all target geographies. Although this too will cause a testing expenditure – if design deficiencies are identified early, downstream or final product testing costs will be lowered.

### **Mutual Recognition:**

During compliance review processes, identification of mutual recognition of test reports will lower overall compliance costs. Many times, previously developed products that have undergone testing will utilize common parts/components that will be used in the new product. Although final designs are important and must be evaluated, it is highly probable that previous testing may be re-used or, accepted under some mutual recognition agreement. A primary example of mutual recognition of test reports is The CB Scheme. Accepted by at least 44 countries, under the CB Scheme, if product is covered by one of numerous IEC Standards and was tested at a Certified Test Lab (CTL) as accredited by the country’s National Certification Body, (CB); it is highly probable the test report may be incorporated into the new product’s test plan.

### **Choosing a Test and Certification Partner:**

When selecting a test and certification partner, the following criteria should be used:

#### **1. Accreditations.**

- a. Many Laboratories claim that they are accredited to ISO 17025 “General Requirements for the competence of testing and Calibration Laboratories”. This means that this Laboratory has undergone and is in compliance with the requirements of an independent third party accreditor such as: NAVLAP, A2LA or has undergone an assessment by a peer assessment team in the international CB Scheme. The assessment is usually conducted to certain list of standards. It is never such that it covers all standards. If the Laboratory claims that they are accredited to all standards – ask for proof of such accreditation.
- b. Compliance means that the laboratory has the necessary test equipment; has adequately trained its personnel and follows the quality procedures outlined in ISO 17025. Additional accreditations may be required for equipment with specific requirements, such as FCC Schemes. Written evidence should be requested.
- c. The Certification Bodies must be accredited to ISO Guide 65 “General Requirements for Bodies Operating Product Certification Systems.

#### **2. Location**

- a. It is very convenient if the laboratory is located in the same geographic and time zone as the manufacturer. This will help with communications and lower expenses for the shipping of test samples.
- b. If the products are tested at the manufacturer’s premises – the travel expenses for the test engineers and auditors should be evaluated.

### **3. Global Reach**

- a. Before engaging the certification lab it is recommended that one investigate its accreditation portfolio with regards to obtaining National Certificates. In many instances, organizations claim that they have MRA's or personnel in the countries of interest, but at the end it appears that the processes for obtaining the certificates in a timely manner has not developed.

### **4. Equipment and Facilities**

- a. Before engaging a test lab, make sure that the lab has adequate facility for your product as the test chambers may be too small for your product or, the laboratory cannot provide the required "Power and/or Environmental Conditions" mandated by the standard for your particular product and test.
- b. If the environmental conditions or test equipment do not meet the requirements of the standard – your product may show failures, which are actually resultive of the test environment.

### **5. Personnel and Service**

- a. When dealing with the Laboratory – service is a key issue. Here you really need a responsive professional who understands the pressures of getting a compliant product into the market. If the lab simply puts you on a waiting list and then ignores your internal schedules you have not found a "partner".
- b. Otherwise, it is important to understand that the test engineer is not the person who designed the product; thus the more information that is supplied to him/her prior to the testing evaluation the more probable it is that the test experience will be positive.

### **6. Follow-Up**

- a. It is critical that the manufacturer maintain accurate and timely records for the maintenance of certificates, etc. If the product is Certified or Listed, it is the manufacturer's responsibility to ensure that all ongoing quality procedures are followed such that during subsequent evaluations the production line and produced product is identical to the one originally tested.
- b. If a critical component replaces an original component that was not originally tested – the laboratory must be notified, to determine if there is a need for additional testing.

If production line tests are required – they must be conducted in the manner prescribed in the "Instructions by the Test Lab" and use equipment that is calibrated in the same manner.

Utilizing a product test and certification lab involves two-way communication and understanding. The manufacturer is not an innocent bystander in the process, but rather an active participant.

To summarize:

1. Conduct early research to select the correct test and certification provider.
2. Think globally
3. Engage the selected lab early.
4. Ask questions often.
5. Provide information in a timely and complete manner.
6. Assist and answer questions during product evaluation
7. Always keep compliance in mind
8. Do not make changes to the product without first consulting your test and certification provider.

For further information or to schedule a conference with SIMCOM International please contact SIMCOM at: (678) 690-8540 or, [service@esimcom.com](mailto:service@esimcom.com) or, visit us at: [www.esimcom.com](http://www.esimcom.com)

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## **Obstacles Preventing Sales to China**

Your company has obtained the appropriate regulatory approval (CCC Marking, Pattern Approval, or Network Access License) for your product. Your company ships one million plus units thinking you have the green light to begin saturation of the market. This shipment goes through without a hitch, but the second shipment of a million units is stopped at customs. A few days after shipment your customer contacts you because the shipment has not arrived as promised. Panic begins to sets and emails begin to fly around the organization as to why the shipment got stopped. Engineering chimes in that the machine has the appropriate regulatory approval. Now more than ever your company needs to due diligence against additional burdens or barriers as China is implementing additions laws that manufacturers must comply with for legal sales.

The latest law causing quite a stir is the sales permit required for all security products. This article will help your company better understand the requirements and scheme behind the sales permit.

Others that seem to be of interest are the Chinese Product Quality and Consumer Interest Protection Laws. These will be discussed in a later edition of the GCN.

### **Sales Permit for Security Products**

The Ministry of Public Security (MPS), run by the Chinese government has tight control over security products made by foreign manufacturers. MPS announced 11 types of security products requiring testing and certification to MPS standards.

- Access control products: firewalls, routers, proxy servers/ gateways
- Authentication products
- Security auditing products
- Security management products
- Data integrity products
- Digital signature products
- Nonrepudiation products
- Commercial encryption products
- Tempest products
- Information system security
- Information security services

The process of applying for MPS approval includes two steps:

- a) product testing and evaluation at an MPS-assigned test lab or research center
- b) application for an MPS sales permit at an MPS Certification Center.

The approval is granted upon successful completion of documentation submittals and type-testing in the form of a sales permit.

At this time, the following documents must be submitted to the test lab and application office, but may change over time:

- Signed contract between the local legal representative and the test facility
- Business licenses of the manufacturer and the local legal representative



- Product documentation covering: configuration management, delivery and operation, development process, instruction manuals, product self-testing and evaluation, weakness analysis or appraisal of the product, etc.
- Approvals from other countries (if there are any)
- Power of attorney
- Cover letter identifying the person of contact for such an application

It is advised to use a Consultative Agent approved by the Chinese government. Passing required tests does not guarantee MPS approval. It wise to make sure that your agent has discussed your application with the MPS Application office for approval prior to testing.

<b>Comparison of CCC, MII, and MPS Approvals</b>			
<b>Important Questions</b>	<b>CCC</b>	<b>MI</b>	<b>MPS</b>
Are documents required in Chinese?	Yes	Yes	Yes
Is there a labeling requirement?	Yes	Yes	Yes
Is there any safety requirement?	Yes	No	Yes
Is there any EMC requirement?	Yes	No	Yes
Is there any telecom requirement?	No	Yes	No
Is there any quality requirement?	Yes	Yes	No
Must testing be performed in China?	Yes	Yes	Yes
Are all different models tested?	Yes	Yes	Yes

Several factors affect MPS approval times and most manufacturers can complete in four to twelve weeks. As with most schemes, testing cost vary due to previous testing and complexity of the product. To conclude the certification process the agent or manufacturer must obtain the MPS sticker with the certification number to be affixed on the approved product.

China is a maze and even with entry in the WTO has managed to create some barriers for foreign manufacturers in order to give advantage to domestic manufacturers. For those companies, not currently in the Chinese market be prepared for the difference in culture, laws and regulations, and the need for flexibility to change. The use of a Consultative Agent can help you overcome these hurdles as well as with any of the Chinese Certification Schemes.

For more information contact a SIMCOM representative at [chinaservices@esimcom.com](mailto:chinaservices@esimcom.com) or, (678) 690-8540

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## ARGENTINA

Argentina is a longstanding stable democracy with robust economic growth, and competitive, skilled and highly educated labor force. Companies will encounter excellent opportunities to do business successfully in this country.

**Natural Resources:** Fertile plains (pampas); minerals --lead, zinc, tin, copper, iron, manganese, oil, and uranium.

**Primary Industries:**

- Agriculture (9% of GDP, about 50% of exports by value, including agribusiness): Products --grains, oilseeds and by-products, livestock products.
- Industry (22.3% of GDP): Types --food processing, oil refining, machinery and equipment, textiles, chemicals and petrochemicals.

**Imports:** \$22.3 billion in 2004 - Machinery, vehicles and transport products, chemicals

**Major Trading Partners:** MERCOSUR 36.8%; EU 18.8%; NAFTA 19.4%. Imports from the United States were 15.4% of total Argentine imports, and 79.4% of Argentine imports from NAFTA in 2004.

**Exports:** \$34.5 billion - Grains, meats, oil seeds, fuels, manufactured products

**Electrical Requirements:**

Frequency 50 Hz

Voltage 220V (Single Phase);

380V (Three Phase)

Plugs must comply with IRAM standards (IRAM 2063 for 2 poles, class II or IRAM 2073 for 3 poles, class I)

Before 1998 compliance with electrical safety requirements in Argentina was mandated for a limited range of electrical products, so, many electrical equipment manufacturers became accustomed to a relatively unhindered market access. Today, however, several countries in this region have implemented mandatory certification requirements. In Argentina, since August 1998, almost all low-voltage electrical equipment has been covered by the mandatory requirements of Resolution 92/98 of the State Department of Industry, Commerce, and Mining. It is the responsibility of manufacturers, importers, distributors, and suppliers to ensure the certification of their products by demonstrating that they meet the essential safety requirements. The proof of Compliance is verified by Customs.

**Procedure for Noncompliant Equipment Arriving in Customs.**

In cases where the State Customs Office verifies lack of compliance with the resolution's requirements, it will be possible to release the merchandise "without permission to be used" (under the terms of Law No. 22.802), as long as the importer takes the necessary steps to rectify the situation.

To take the steps, the importer must inform the State Office for Home Trade, by means of a sworn declaration, of the quantity and type of merchandise, its country of origin, and the place where it will be stored until it is brought into compliance with the regulations that are in force.



Within 60 days following the withdrawal of the merchandise under the conditions described, the importer must make the Declaration of Conformity to Type, or obtain a Certificate of Conformity, and present it to the State Office for Home Trade, which will authorize the release of the merchandise for sale and subsequent use, within 10 days of receipt of the correct documentation.

**Mandatory Regulations**

### Resolution 92/98

Resolution 92/98 covers all low-voltage electrical devices, equipment, or appliances that have a nominal voltage up to 1000 V ac or 1500 V dc. All products sold in Argentina that have an external power supply must meet the requirements of Resolution 92/98 with respect to the power supply.

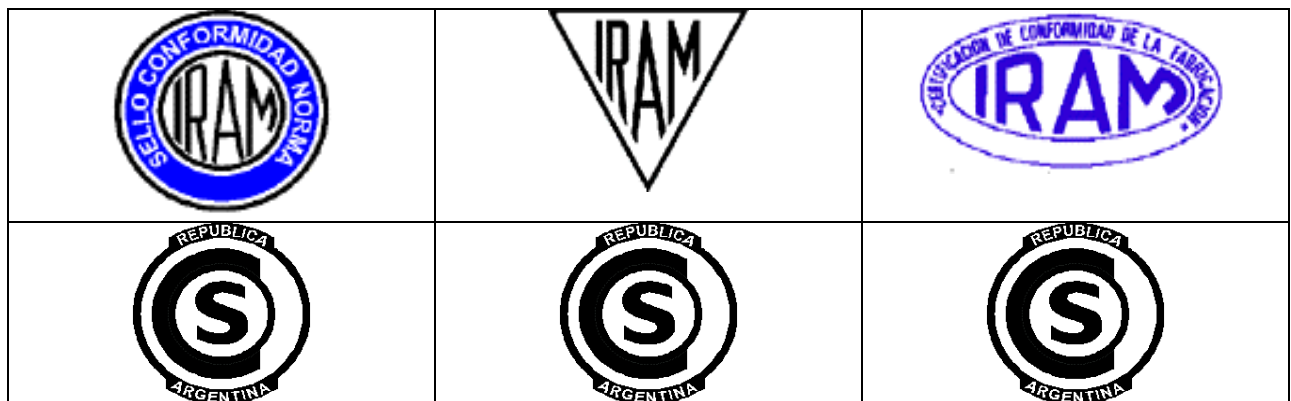
The Resolution 92/98 was implemented in three stages. In this final stage, all products covered by the resolution must have a product certificate issued under a conformity marking scheme aligned with the model described in ISO/IEC 28 (IRAM 354) and issued by an Argentine accredited Certification Body

The main Certification Body in Argentina is IRAM - a non-for-profit private association founded on 1935. It is the National Standardization Body of Argentina and also operates certification activities under an independent management. IRAM represents Argentina at ISO-International Organization for Standardization, AMN-Mercosur Association for Standardization and COPANT-Pan-American Commission of Technical Standards, and manages together with the Argentine Electro-technical Association the Argentine National Committee of the IEC.

According to the current Certification Rules in Argentina, IRAM certifies electro-technical products by granting the following IRAM Certification Marks:

From left to right:

1. IRAM Mark of Conformity with IRAM Standard - Granted on the basis of a product compliance with a National IRAM Standard;
2. IRAM Safety Mark - Granted on the basis of compliance with Safety Requirements of a National IRAM Standard or an IEC Standard;
3. IRAM Certification of Manufacturing Conformity Mark - Granted on the basis of the compliance with an IEC or other foreign (National) Standard



The Applicant for one of IRAM National Marks can be a:

- Foreign Manufacturer directly, or
- Commercial Agent

The CB Scheme Test Certificates and Reports are accepted for Review and Recognition.

IRAM has signed MRA's with quite a few foreign Certification Bodies. So, depending on the product and the contents of the MRA a sample of the product may or may not be required in advance when a CB Test Certificate is presented for national recognition.

Pre-License Inspection of the Manufacturing Facility is required. Once the license is granted, follow-up inspections to factory are also required.

The IRAM License is valid indefinitely, based on the fact that the product and the requirements for the product are the same, that the no non-compliances found during Follow Up Inspections and that all the Fees are paid and up-to-date. If these conditions are met, the License is automatically extended every year.

#### **Available Certification Schemes:**

- a) Mark certification (System 5)
- b) Type certification (System 4)
- c) Lot certification (System 7)

With the implementation of Resolution SCT N° 197/2004 published in January 7th 2005, each product certified by either Argentina S-mark, Type or Lot approval, must exhibit a safety symbol identifying the corresponding certification scheme.

The type designation and trademark of the product shown in its packaging and/or rating labels must be identical to the type designation and trademark listed in the certificate.

The symbols should be shown as following:

- Type Approval: the type approval symbol includes the basic CS, which stands for “seguridad comprobada” meaning “in compliance with safety”, together with the letter “T” and the certificate number as optional. The Certification Body logo should not be placed next to the symbol.
- S-Mark approval: the S-Mark approval symbol includes the basic CS along with the proprietary logo of the accredited certification body (as shown above), and the certificate number is optional.
- Lot Approval: the Lot approval symbol includes the basic CS along with the letter “L”, the lot number, and the certificate number as optional. The Certification Body logo should not be placed next to the symbol.

According to article 1 of Resolution 109/2005, the above-referenced symbols must be permanent and visible on each of the products involved, at the time of commercialization in Argentina.

The only exemption to this Rule is, when the dimensions of the product do not allow such placement, or when the reduced size of it makes the identification of the symbol unreadable. In these cases the symbols can be exhibited on the packaging, wrapper or labels.

The safety symbols can be exhibited accompanied by the certificate number of the certified product.

#### **Products, subject to mandatory testing/certification per Resolution 92/98:**

These products must comply with a “Mark certification Scheme”:

- Cables for fixed installations
- Circuit breakers for over-current protection
- Earthing installation material
- Fuses
- Incandescent and fluorescent lamps
- Insulating ribbon
- Plugs for domestic use
- Residual current circuit breakers
- Sockets for domestic use, fixed and portable types switches

These products must comply with any of the three Certification Schemes, depending on the Terms of Importation in Argentina:

- Air conditioners
- Appliances for heating liquids (coffee makers, kettles, fryers)
- Electrical heaters
- Electrical irons
- Electrical shavers
- Kitchen appliances (food processors, blender, mixers)
- Lamp-holders, sockets, starter-holders
- Portable electrical tools
- Range hoods
- Refrigerators, ice-makers, freezers
- Skin and hair care appliances Clothes dryers
- Dishwashers
- Electrical instantaneous water heaters
- Electrical storage water heaters
- Fans
- Gas appliances with electrical devices
- Household and commercial cooking appliances
- Hydro-washers
- Lawn mowers and hand-held lawn-edge trimmers
- Luminaries
- Microwave ovens
- Vacuum cleaners, scrubbing machines and other devices for floor treatment and cleaning
- Washing machines

**Notes:**

\* Electric and electronic equipment and devices consuming less than 5kva, not included above.

\*\* Materials for electrical installations rated under 63Amp, are not included above

\*\*\*Products rated below than 50V with dual (battery or adaptor) operation, with adaptor provided by the manufacturer must include such adaptor duly certified. The owner's manual must indicate that only the original adaptor provided can be used for safety reasons.

\*\*\*\*In case that the adaptor is not provided by the manufacturer, the main characteristics of the required power supply must be indicated in the owner's manual.

**Most Recent certification requirements for electrical and electronic products according to Resolution 198/2004:**

Resolution 198/2004 establishes the certification requirements for electrical and electronic devices below 50V or above 63A.

Taking into consideration the fact that most electrical and electronic devices operated at a voltage below 50V do not present a potential risk to the user, Resolution 198/2004 lists products that are exempt from the mandatory certification system. It also lists those products, which will need a certificate in order to be sold commercially in the market.

In Resolution 198/2004, products exempt from the mandatory certification system established under Resolution 92/98 are as follows:

- Products with a rated current above 63A
- Products below 50V with battery operated power source
- Products below 50V with an external power supply (including those that may also be operated by batteries), where the following conditions are met:



- ✓ The power supply must have valid certification for the Argentine market.
- ✓ The user manual for the product must indicate the technical characteristics of those power supplies that can be used with the product, or the specific model to be used.
- ✓ The user manual must indicate the risk of using a power supply different from the one specifically indicated.

**It also provides the List of Products below 50V subject to mandatory certification:**

- Luminaries and power source systems for luminaries connected to mains power sources directly at more than 50VAC
- Dichroic lamps and its lamp holders
- Hand held battery operated power tools
- Electric fence energizers
- Muscle stimulators for fitness activity
- Lighting ancillary equipment (inductive and electronic)

**General Conditions for Product Certification.**

Any instructions for use that must be observed in order to ensure safe operation should appear on the equipment itself. If this is not possible, these should appear on an instruction sheet supplied with the equipment. In both cases, these instructions must be in the national language.

The equipment must be marked with the manufacturer's name or registered trademark and address, the name and address of the local distributor or importer, and the name or model number of the equipment. If this is not possible, the manufacturer's name or trademark and the equipment's model number must be marked on the equipment itself, and the other details must appear on the packaging.

The equipment and its constituent parts must be manufactured in a way that guarantees that it can be connected safely and correctly.

The isolation class must be adequate for the intended use and the conditions of use of the equipment. Isolation classes 0 and 01 are forbidden.

Components that are to be integrated through a manufacturing or assembly process into a product covered by the same legislation are not to be subject to the requirements of the directive when they enter the country. If they are to be sold on the internal market, however, they must meet the requirements of the resolution.

This exemption also applies to those products that come into the country under a temporary import permit, such as product test samples.

**Telecom & Radio Equipment**

In Argentina, telecommunications equipment must comply with specific standards and regulations that are developed and established by the National Communications Commission (CNC). Compliance with these standards is accomplished through type approval process. Approved telecommunications equipment is listed in the Register of Telecommunication Equipment and Activities, which is controlled by CNC.

CNC approval is required for all terminal equipment that is to be connected to the public network. Most radio equipment also must have this approval.

## Medical devices

In accordance with Medical Device Resolutions 607/93 and 255/94: Medical products in Argentina must be registered with ANMAT (The National Administration of Drugs, Foodstuffs, and Medical Technology). Additionally, electrical medical devices must comply with electrical safety requirements of country of origin (e.g. FDA for US). Currently, it appears that there is no certification marking or certificate that is issued by ANMAT upon registration of the medical device. **Note:** most electro-medical devices are excluded from Resolution 92/98. The devices that do fall within the scope of this resolution must comply with its requirements.

For further information or to schedule a conference with SIMCOM International please contact SIMCOM at: (678) 690-8540 or, [service@esimcom.com](mailto:service@esimcom.com) or, visit us at: [www.esimcom.com](http://www.esimcom.com)

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CNCA Announces Implementation Rules for WLAN products. **Very soon an English version along with correlating GB Standards will be available on our website:**

[http://www.esimcom.com/aak2\\_0\\_1\\_2/simcom\\_about/ab4\\_IQ\\_china\\_standards.asp](http://www.esimcom.com/aak2_0_1_2/simcom_about/ab4_IQ_china_standards.asp)

## Is your company ready for China's latest regulatory barrier?

China's RoHS requirements are more stringent than the EU and are fast approaching with a deadline of March 1, 2007. New information has been released from MII answering some of the hottest questions. Below are sample questions as well as information about a service to eliminate all your questions along with extensive training on this subject.

**Q: According to Article 18 of the Administrative Measure, it seems that all electronic information products entering into the market need compulsory certification of toxic and hazardous substances. A certification process is not mentioned in the Administrative Measure. Will certification increase the burden for manufacturers, distributors, and importers?**

**A:** Since the Administrative Measure is to restrict and/or prohibit toxic and hazardous substances in electronic information products under a Catalogue Administration Model; only catalogue-listed products will be required to have 3C certification. At the beginning of implementation (effectiveness) of the Administrative Measure those products not listed in the catalogue do not need 3C certification. As this is a gradual process, enterprises will have enough time to prepare. There is no question that 3C certification for catalogue listed products will increase production cost. To enterprises, the requirements are the same to Chinese enterprises and foreign enterprises, manufacturers, retailers, importers.

**Q: The EU RoHS focuses on end products. Does the Administrative Measure also focus on end products? Does it include all the products in the supply chain?**

**A:** The Administrative Measure covers all the products in the supply chain including parts and components. Although electronic components and materials are not end products; these products may include toxic and hazardous substances, which may pollute the environment. And thus they are covered in the Administrative Measure.

Do you want to see more question and answers provided by MII on this subject? If so please login in or register on our website at:

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- ✓ Detailed monthly reports on the Chinese government's development activities for the "Electronic Information Products Administrative Measure"
- ✓ Subscriber forum
- ✓ An "Educational Series" on how to implement a "Best Practices Approach"
- ✓ Inside information on China's Standard Development of:
  - Label Standards
  - Threshold Limits of Restricted Substances
  - Implementation Procedures

Click on the following [SIMCOM's China RoHS Services](#) or contact a SIMCOM representative at 678 690-8540 or [service@esimcom.com](mailto:service@esimcom.com).

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## *International Compliance News*

### **Korea's Product Identification System Changes**

The Korean Ministry of Information and Communication (MIC) recently announced a change to their certificate ID numbering system for information technology and telecommunication terminal equipment. The new system similar to the Federal Communications Commission (FCC, US) will be implemented on October 1 of this year. MIC will supply the certificate ID number for applications after this date prior to the certificate being issued.

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### **Automotive EMC Directive Amended**

Recently the EU removed the requirements for the use of 79 GHz short- range radar while modifying the use of 24 GHz radar equipments. In addition, amendments were issued to ensure consistency with existing amendments to Automotive EMC Directive related to motor vehicles and their trailers.

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### **NEW EMC Directive to have Guidance Document**

The new EMC Directive (2004/108/EC) was adopted the European Parliament and the Council of the European Union. On July 20, 2007, all references will refer to the new directive while the current EMC Directive (89/336/EEC) will be repealed. Apparatus compliant will the original EMC Directive will not be allowed into the market after July 20, 2009.

A draft Guidance Manual consisting of 61 pages details the 14 pages of the new EMC Directive will be available soon. Please contact SIMCOM for a copy at:  
[service@esimcom.com](mailto:service@esimcom.com)

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## **IEC to Address Nanotechnology Standards**

International Electrotechnical Commission's Standardization Management Board recently agreed to create the Technical Committee 113 to address the field of nanotechnology. The job of TC 113 is to prepare standards on electricity and other technologies pertinent to IEC as it relates to nanotechnology. TC 113 will discuss and meet with other IEC Technical Committees, regional, national, and international standardization organizations. Careful review will be given to ISO TC229 "Nanotechnology" in order to prevent duplication.

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